Supreme Court, U.S.
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No. 87-1496

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

RACHELLE LABORATORIES, INC.,

Petitioner,

v.

ANITA OSBURN, INDIVIDUALLY AND AS INDEPENDENT EXECUTRIX OF THE ESTATE OF CLOIS DALE OSBURN, DECEASED

Respondent.

On Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF IN OPPOSITION

Counsel of Record for Respondent

DALE DOUGLAS WILLIAMS
WILLIAMS, PATTILLO & SQUIRES
3501 West Waco Drive
Waco, Texas 76710
(817) 752-9966

TABLE OF CONTENTS

	Page
Table of Contents	i
Table of Authorities	ii
Constitutional, Statutory and Regulatory Provisions Involved	2
Statement of the Case	4
Reasons for Denying the Writ	6
Conclusion	19
Appendix	A-1
Warning Section to Rachelle's Package Insert to Veterinarian	A-1

TABLE OF AUTHORITIES

Page

A. Cases

Abbott v. American Cyanamid Co., No. 86-857-A (E.D. Va. Mar. 9, 1987) 15

Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981) 14

Chicago & N. W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 101 S. Ct. 1124, 67 L. Ed. 2d 258 (1981) 16

Cosmetic, Toiletry and Fragrance Association, Inc. v. State of Minnesota, 440 F. Supp. 1216 (D. Minn. 1977), aff'd, 575 F.2d 1256 (8th Cir. 1978) 15

Ezagui v. Dow Chemical Corp., 598 F.2d 727 (2nd Cir. 1979) 14

Florida Lime and Avacado Growers, Inc. v. Paul, 373 U.S. 132, 83 S. Ct. 1210, 1217, 10 L. Ed. 2d 248 (1963) 16

Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 210-11, 6 L. Ed. 23 (1824) 16

Grocery Manufacturers of America, Inc. v. Gerace, 755 F.2d 993 (2nd Cir.), aff'd, 474 U.S. 801, cert denied, 474 U.S. 820 (1985) 15

Graham v. Wyeth Laboratories, Inc., 666 F. Supp. 1483 (D. Kan. 1987) 15

Hines v. Davidowitz, 312 U.S. 52, 61 S. Ct. 399, 401, 85 L. Ed. 581 (1941) 17

Hurley v. Lederle Laboratories, 651 F. Supp. 993 (E.D. Tex. 1986) 15

Jeski v. Connaught Laboratories, No. A-84-CA-395 (W.D. Tex., Dec. 18, 1986) 15

TABLE OF AUTHORITIES — (Continued)

	Page
Milam v. American Cyanamid, No. 4-85-92-K (N.D. Tex. Oct. 15, 1986)	16
Morris v. Parke-Davis and Co., No. 82-5296-RJK (C.D. Cal. Sept. 19, 1985), 677 F. Supp. 1332 (C.D. Cal. 1987)	15
National Women's Health Network, Inc. v. A. H. Robins Co., Inc., 545 F. Supp. 1977 (D. Mass. 1982)	15
Pacific Gas and Electric Co. v. State Energy Resources Conservation and Dev. Comm'n., 461 U.S. 190, 103 S. Ct. 1713, 1722, 75 L. Ed. 2d 752 (1983)	17
Parke-Davis v. Stromstadt, 411 F.2d 1390 (8th Cir. 1969)	14
Patton v. Lederle Laboratories, 655 F. Supp. 745	15
Salmon v. Parke, Davis & Co., 520 F.2d 1359 (4th Cir. 1975)	14
Silkwood v. Kerr-McGee, 464 U.S. 238, 104 S. Ct. 615, 621, 78 L. Ed. 443 (1984)	17
Smith v. Wyeth Laboratories, No. 84-2002 (S.D. W. Va. Aug. 21, 1986)	15

TABLE OF AUTHORITIES — (Continued)

Page

B. Statutes and Regulations

U.S. Const. Art. 6, Cl. 2 2

21 U.S.C. § 331 (1972) 2

21 U.S.C. § 352 (1972) 2, 10, 11, 12, 13

21 U.S.C. § 353 (1972) 3, 8, 10

21 C.F.R. § 201.105 (1987) 3, 7 11, 12

21 C.F.R. § 514.8 (1987) 13

43 Fed. Reg. 4214 (1978) 16

51 Fed. Reg. 1367 (1986) 18

C. Other Sources

1951 U.S. Code Cong. & Adm. News, p. 663 10

1951 U.S. Code Cong. & Adm. News, p. 2457 8

1951 U.S. Code Cong. & Adm. News, p. 2461 11

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BRIEF IN OPPOSITION

Respondent respectfully submits this Brief in Opposition to the Petition for a Writ of Certiorari to review the Judgment and Opinion of the United States Court of Appeals for the Fifth Circuit entered on August 28, 1987.

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

U.S. Const. Art. 6, Cl. 2

Supreme Law of Land

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made under the Authority of the United States, shall be the Supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 331

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 352

A drug or device shall be deemed to be misbranded —

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the

public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 U.S.C. § 353

(b) (1) A drug intended for use by man which —

(B) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;

(4) A drug which is subject to Paragraph (1) of this subsection shall be deemed misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription."

21 C.F.R. Part 201 Labeling

Subpart D — Exemptions from Adequate Directions for Use

§ 201.105 Veterinary Drugs

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(a) The drug is:

(1) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail

distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or

(2) In the possession of a licensed veterinarian for use in the course of his professional practice.

(b) The label of the drug bears:

(1) The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";

STATEMENT OF THE CASE

When Clois Osburn was diagnosed as having leukemia, he was forty-two years old. For almost the entirety of his adult life, he had worked as a cowboy in the Texas Panhandle, often caring for sick cattle and horses. In September, 1982, Osburn obtained from a veterinarian a prescription for Veterinary Chloramphenicol Oral Solution, an antibiotic, which he immediately began administering daily to the sick calves he was caring for. Over the following eighteen months, he used ten to thirteen cases of chloramphenicol, each containing six sixteen ounce bottles of the antibiotic. Of this total, eight to ten cases consisted of chloramphenicol produced by Petitioner Rachelle and the other two or three cases were of chloramphenicol produced by Anchor Laboratories, Inc.

Since the chloramphenicol came in plastic capped bottles into which a needle could not be inserted, each morning Osburn poured several bottles of the drug from their original bottles into other, same sized bottles with injectable rubber lids. These he carried in a medicine bag on the horse's saddle to pastures where the calves grazed. To administer the drug, Osburn straddled the sick animal, inserted a syringe into the

rubber lid of a bottle containing chloramphenicol, filled it, and injected the calf with a 60 cc. syringe-full dose of the drug. In the process of filling the syringe, chloramphenicol leaked from previously made syringe holes in the rubber lid. The chloramphenicol often ran down Osburn's hand and arm, getting into scratches and cuts on his arm. Osburn recalled that on one occasion so much of the drug got into a rope burn on his arm that he could taste its bitterness in his mouth. Osburn wore leather gloves on the job, and testified that by the end of each day the gloves were soaked through with chloramphenicol.

The labels on the bottles of chloramphenicol produced by Rachelle and Anchor contained no warnings of any health hazards to humans as a result of exposure to the drug.

In late February, 1984, after 18 months of exposure to Rachelle's drug, Clois Osburn was diagnosed as having leukemia. The doctors informed Osburn that from the date of diagnosis he could expect to live two to five years.

On August 8, 1984, Mr. and Mrs. Osburn filed suit against Rachelle and Anchor. Subsequently, Rachelle and Anchor filed cross-claims against each other for contribution. The Defendants then impleaded Dr. Jack Swain, the veterinarian from whom Osburn obtained the chloramphenicol, demanding indemnity and contribution. Shortly before trial, the Osburns reached a settlement agreement with Anchor and Dr. Swain.

The Osburns tried their case against Rachelle on December 2-6, 1985. Rachelle's Motion for Directed Verdict at the close of all the evidence was denied. Answering Special Interrogatories, the jury found that Rachelle had failed to provide adequate warnings to Mr. Osburn regarding the risk of fatal blood disorders from absorption of chloramphenicol, that this failure was a producing (and proximate) cause of

Osburn's leukemia, and, therefore, that Rachelle was liable under both strict products liability and negligence theories. Pursuant to the District Court's instruction that if it found Rachelle liable, then as a matter of law Anchor was also liable, the jury apportioned causation at 85% attributable to Rachelle and 15% attributable to Anchor. The jury awarded $2,500,000 damages to Clois Osburn and $500,000 damages to Anita Osburn. On January 2, 1986, the District Court entered Judgment for the Osburn's against Rachelle, awarding all damages minus the 15% attributable to Anchor for a total judgment of $2,550,000. Rachelle moved for Judgment Notwithstanding the Verdict, and for New Trial or, Alternatively, a Remittitur. The District Court denied these motions and Rachelle appealed to the United States Court of Appeals for the Fifth Circuit. The Fifth Circuit affirmed the Judgment below subject to a Remittitur of approximately $547,000.

Clois Osburn died of leukemia on July 20, 1987 and his wife, Anita Osburn, as Independent Executrix of the Estate of Clois Osburn, filed her consent to the Remittitur.

REASONS FOR DENYING THE WRIT

The Court should deny the Writ of Certiorari to consider the questions presented by Petitioner because both questions are based upon a false and misleading interpretation of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq. (The "FDCA") and the FDA regulations issued pursuant to the statute. Secondly, the Fifth Circuit's opinion is consistent with every other circuit court that has considered the issue of whether or not the FDCA preempts a state tort law damage claim based upon the failure to provide adequate warnings. The Fifth Circuit's opinion is correctly decided upon the traditional preemption analysis established by this Court. Furthermore, the specific regulations regarding oral chloram-

phenicol have been repealed and the product is no longer being produced and sold in the United States and, therefore, this case does not warrant the significance of Supreme Court review.

I.

PETITIONER'S QUESTIONS PRESENTED MISINTERPRET THE FDCA AND THE FDA REGULATIONS

A.

PETITIONER'S FIRST QUESTION PRESENTED

"Whether the mandatory federal regulations prescribing a specific warning to lay users administering veterinary chloramphenicol oral solution preclude a state law damage action based upon the alleged inadequacy of that warning?"

First, the FDA has never prescribed a specific warning to lay users of veterinary chloramphenicol. Secondly, the state law damage action was not based upon the inadequacy of any FDA prescribed warning. A review of the FDA regulations and the actual warning used by Petitioner will demonstrate the falsity of Petitioner's assumptions in question one.

What federally mandated "specific warning to lay users" is Petitioner referring to in its first question presented? The FDA requires all prescription veterinary drugs to bear the prescription legend: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." 21 C.F.R. § 201.105 Rachelle asserts on page nine of the Petition that this is the "specific warning to lay users" that it is referring to.

This prescription legend is not a specific warning of any hazard to humans, nor is the statement even directed to the

lay user. There is no legislative history detailing the purpose of this prescription legend in veterinary drugs because this requirement was issued as a regulation and not a statute. However, there is an enlightening legislative history discussing the almost identical prescription legend required for human prescription drugs in Section 503(b)(4) of the Food Drug and Cosmetic Act. All prescription drugs for use by man are required to bear this statement: "Caution: Federal law prohibits dispensing without prescription." The legislative history states:

> "All drugs covered by the three classifications of prescription drugs must bear a label containing the statement: 'Federal law prohibits dispensing without prescription.' This gives the retail druggist clear notice that he will be in violation of the Federal Food, Drug and Cosmetic Act if he dispenses any drug so labeled without a prescription." (Emphasis added) 1951 U.S. Code Cong. & Adm. News, p. 2457

Clearly, the prescription drug legend required on all veterinary prescription drugs is required to put the retail seller of veterinary drugs on notice that he cannot sell this antibiotic to anyone who wants to buy it. He can only sell it to a veterinarian or to a customer who has a prescription from a veterinarian. Otherwise, he will be in violation of the Federal Food, Drug and Cosmetic Act.

Petitioner's attempt to characterize the prescription drug legend as a federally mandated "specific warning to lay users" is not only inconsistent with the purpose of the legend, it is inconsistent with its own labeling in this case. Contrary to the position now asserted by Petitioner before this Court, there was an actual warning that was drafted by Petitioner (not the FDA) and placed on the bottles of

chloramphenicol used by Clois Osburn. The warning on the bottle stated:

> "WARNING: Not for use in animals raised for food production. Keep out of reach of children. Protect from light and freezing."

This warning was the *only* warning that was contained on Petitioner's toxic drug. The oral chloramphenicol bottle, with this warning label, was admitted into evidence (Plaintiff's Exhibit No. 1) and this is the warning label that was found to be inadequate by the jury. Petitioner's brief somehow ignores the only warning contained on their product. Petitioner's attempt to characterize the prescription drug legend as a federally mandated "specific warning to lay users" and its attempt to lead the Court to believe that the state law damage claim was based upon the inadequacy of the prescription drug legend are false. Petitioner's first question presented is not worthy of review by this Court.

B.

PETITIONER'S SECOND QUESTION PRESENTED

"Whether state tort law can override an explicit federal regulatory determination that veterinary drug manufacturers cannot and should not attempt to formulate and direct detailed, specific warnings and instructions to lay users administering a veterinary drug."

First, the FDA has never made a regulatory determination that veterinary drug manufacturers cannot and should not attempt to formulate direct, detailed and specific warnings that are necessary for the protection of those who administer the drugs to animals on the prescription of a veterinarian. Secondly, Congress has never given the FDA the statutory authority to make such a determination as to veterinary

drugs. Furthermore, such a determination would be inconsistent with the purposes of the Food, Drug and Cosmetic Act to promote the health and safety of the consuming public. A review of the Act and the FDA regulations issued pursuant to the Act will demonstrate the falsity of Petitioner's assumptions in question two.

Section 502(f) of the Food, Drug and Cosmetic Act (21 U.S.C. § 352(f)) requires drug labels to contain two items to avoid a criminal violation of the Act for selling a misbranded drug. First, Section 502(f)(1), requires a drug label to contain *adequate directions* for use. Secondly, 502(f)(2), requires a drug label to contain *adequate warnings* as are necessary for the protection of users. These two requirements are separate and distinct obligations of the drug manufacturer as set out in the FDCA. The statute goes further and allows the FDA to exempt a drug from the requirement of 502(f)(1), *adequate directions* for use, under certain circumstances.

The statute has never given the FDA the authority to exempt any veterinary drug label from the requirement of 502(f)(2), to provide *adequate warnings* as are necessary for the protection of users.

In 1951, Section 503 of the Food, Drug and Cosmetic Act (21 U.S.C. § 353) was amended by Congress to exempt all prescription drugs intended for use in man from the labeling requirements of Section 502(f) and established procedures for the administration of prescription drugs to humans. 1951 U.S. Code Cong. & Adm. News, p. 663 This 1951 amendment did not include veterinary drugs. Drugs intended for use in animals continued to be subject to the requirements of

both (f)(1) directions and (f)(2) warnings. The legislative history of the 1951 amendments make this clear:

> "Under paragraph (1) of the new subsection (b) prescription drugs are defined as drugs intended for use by man which fall into any one of three categories. In limiting prescription drugs to those intended for use by man this new subsection differs from the present law, which refers to prescription drugs to include not only those dispensed by physicians and dentists, but also those dispensed on prescription by a veterinarian. Under the committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, although it will be possible under Section 502(f) to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian. *In the absence of any exempting regulations, these drugs will be subject to the labeling and dispensing requirements of the act applicable to over-the-counter drugs.*" 1951 U.S. Code Cong. & Adm. News, p. 2461 (Emphasis added)

Therefore, in the absence of exempting regulations, veterinary drugs, like over-the-counter drugs, must comply with both 502(f)(1) adequate directions and 502(f)(2) adequate warnings.

In 1975, the FDA exercised its grant of authority under 502(f)(1) and exempted all veterinary prescription drugs from providing adequate directions to the lay user and required adequate directions for animal use to go to the veterinarian. This regulation is found under the heading: *Subpart D — Exemptions from Adequate Directions for Use, Section 201.105 Veterinary Drugs.* 21 C.F.R. 201.105 The regulation states, "a drug intended for veterinary use, which because of toxicity or other potentiality for harmful effect, or

the method of its use, *is not safe for animal use* except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, *shall be exempt from Section 502(f)(1)* of the Act if all of the following conditions are met:" (Emphasis added)

It is clear that the FDA exempted veterinary drugs from 502(f)(1), adequate directions. It is equally clear that the FDA did not exempt veterinary drugs from the requirement of providing adequate warnings necessary for the protection of users under 502(f)(2). As the statute clearly states, Congress does not allow such an exemption of veterinary drugs from 502(f)(2), the requirement to adequately warn users necessary for their protection.

Yet, Petitioner's question assumes that the FDA made "an explicit federal regulatory determination that veterinary drug manufacturers cannot and should not attempt to formulate direct detailed, specific warnings." The question presented is false on its face.

In order to be exempt from providing directions to the lay user under 502(f)(1), the drug manufacturer must provide in a package insert adequate information for use to the veterinarian which information includes precautions, warnings and hazards for *animal safety*. Petitioner's package insert to the veterinarian does include a section dealing with animal safety but contains not a single word relating to warnings or hazards to humans. The relevant section of Petitioner's package insert which provides the precautions and warnings regarding animal safety to the veterinarian has been reproduced in the Appendix on page A-1. Even though this regulation is concerned only with animal safety, Petitioner is relying on this regulation for the proposition that he need only provide warnings to the veterinarian. Contrary to what Petitioner trys to imply to the Court, this is not a case where the drug

manufacturer provided detailed specific warnings regarding human health hazards to the veterinarian, who failed to communicate those warnings to the consumer. On the contrary, Petitioner provided absolutely no warnings to anyone regarding human health hazards associated with exposure to this toxic drug. Yet, Petitioner attempts to hide behind his requirement to provide information regarding animal safety to the veterinarian and concludes that this is an FDA determination that it "cannot and should not" provide warnings necessary for the protection of users as mandated by Congress in 502(f)(2).

Adding further inconsistency to this argument is the fact that Petitioner did include a 502(f)(2) warning on its label as discussed in the first question presented. The 502(f)(2) warning stated:

> "WARNING: Not for use in animals raised for food production. Keep out of reach of children. Protect from light and freezing."

This warning statement was drafted by Petitioner to meet its obligations under 502(f)(2) and was simply found to be inadequate by the jury since it did not warn of health hazards associated with exposure to this toxic drug.

In addition, as was pointed out by the Fifth Circuit opinion, FDA regulations specifically permitted and encouraged Petitioner to add additional warnings to a previously approved label as soon as it became aware of the necessity to do so — without the need to first obtain FDA approval of the supplemental warnings. 21 CFR Section 514.8

As shown above, Petitioner's statutory interpretation is completely inconsistent with the express language, purpose and legislative history of the Food, Drug and Cosmetic Act, and the regulations of veterinary drugs issued by the FDA.

Petitioner's second question presented is not worthy of review.

II.

NO CONFLICT EXISTS AMONG THE CIRCUIT COURTS

Because both of Petitioner's questions presented are based upon false interpretations of the Food, Drug and Cosmetic Act and the FDA regulations, Petitioner's claim that the Fifth Circuit opinion in this case conflicts with other FDCA decisions is illusory at best. As applied to the actual facts of this case, the Fifth Circuit opinion is absolutely consistent with every circuit court which has addressed the issue. The Fifth Circuit found that the FDCA did not preempt a Texas tort law duty to adequately warn users of hazards and risks that were known or that should have been known by the manufacturer. Every circuit court that has considered the identical issue of the preemptive effect of the FDCA as it relates to a state tort law claim of inadequate warnings has found no preemption: *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981) (oral contraceptives); *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727 (2nd Cir. 1979) (DPT and polio vaccine); *Salmon v. Parke-Davis and Co.*, 520 F.2d 1359 (4th Cir. 1975) (chloramphenicol); *Parke-Davis v. Stromstadt*, 411 F.2d 1390 (8th Cir. 1969) (quadrigen vaccination). Each of these cases stand for the proposition that a drug manufacturer's compliance with federal laws and regulations concerning a drug, though pertinent, does not in itself absolve the manufacturer of liability for failure to warn effectively of the drugs' inherent dangers.

Petitioner has failed to cite a single circuit court opinion that has ever held the FDCA to be preemptive of a state tort law claim based upon the inadequacy of a warning approved by the FDA. There simply is no conflict among the circuit

courts as to this issue. Petitioner's reliance upon *Grocery Manufacturers of America, Inc. v. Gerace*, 755 F.2d 993 (2nd Cir.), aff'd, 474 U.S. 801, cert denied, 474 U.S. 820 (1985); *National Women's Health Network, Inc. v. A. H. Robins Co., Inc.*, 545 F. Supp. 1977 (D. Mass. 1982); and, *Cosmetic Toiletry and Fragrance Association, Inc. v. Minnesota*, 440 F. Supp. 1216 (D. Minn. 1977), aff'd, 575 F.2d 1256 (8th Cir. 1978) is misplaced. None of these cases involved a state tort law claim based upon a failure to provide adequate warnings.

Petitioner does cite two district court memorandum opinions finding preemption under the Public Health Service Act and the FDCA relating to the adequacy of the federally written and mandated warnings on DPT shots. Petitioner relies upon *Hurley v. Lederele Laboratories*, 651 F. Supp. 993 (E.D. Tex. 1986) and *Abbott v. American Cyanamid Co.*, No. 86-857-A (E.D. Va. Mar. 9, 1987). However, as was pointed out recently in *Graham v. Wyeth Laboratories, Inc.*, 666 F. Supp. 1483 (D. Kan. 1987), the *Hurley* and *Abbott* opinions were written prior to the publication of the legislative history of the National Childhood Vaccine Injury Act (NCVIA), which legislative history clearly demonstrates congressional intent not to preempt "state tort remedies for vaccine related injuries, despite broad federal legislation and the manufacturers' compliance therewith." (*Graham*, at page 1492) In fact, the court in *Morris v. Parke-Davis and Co.*, No. 82-5296-RJK (C.D. Cal. Sept. 19, 1985) had found preemption prior to the publication of the NCVIA legislative history but has since withdrawn its finding of preemption and entered a new order finding no preemption. *Morris v. Parke-Davis and Co.*, 667 F. Supp. 1332 (C.D. Cal. 1987) The remaining district courts that have considered the issue have found no preemption. *Patton v. Lederele Laboratories*, 655 F. Supp. 745; *Smith v. Wyeth Laboratories*, No. 84-2002 (S.D. W. Va. Aug. 21, 1986); *Jeski v. Connaught Laboratories*, No. A-84-CA-395,

(W.D. Tex. Dec. 18, 1986); *Milam v. American Cyanamid*, No. 4-85-92-K (N.D. Tex. Oct. 15, 1986).

Furthermore, even where the FDA has drafted a specific warning to go on the label of a drug, the FDA recognizes that a jury may challenge the adequacy of the warning and state tort law is not preempted. In 1978 the FDA issued a regulation requiring oral contraceptive drug products to bear a specific warning drafted by the FDA. The FDA issued a final ruling in which the FDA discussed the legal effect of the FDA mandated warning. The ruling states,

> "The fact that patient labeling may have been required and drafted by FDA would not protect the manufacturer from an adverse jury determination on the issue of adequacy." Federal Register, Vol. 43, No. 21, p. 4214.

Except for the two district court opinions relating to DPT cases decided prior to the publication of the legislative history of the NCVIA, all circuit courts and all remaining district courts find no preemptive intent either express or implied in the FDCA. This has been the consistent holding of the federal courts and the interpretation of the FDA for the fifty year existence of the FDCA as it relates to a state tort law claim based upon an inadequate warning.

III.

THE DECISION BELOW WAS CORRECTLY DECIDED

The Fifth Circuit's opinion was based upon the preemption analysis established by this Court in *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 210-11, 6 L. Ed. 23 (1824), and further enunciated in *Florida Lime and Avacado Growers, Inc. v. Paul*, 373 U.S. 132, 83 S. Ct. 1210, 1217, 10 L. Ed. 2d 248 (1963); *Chicago and N. W. Transp. Co. v. Kalo Brick and Tile Co.*, 450 U.S. 311,

101 S. Ct. 1124, 67 L. Ed. 2d 258 (1981); *Hines v. Davidowitz*, 312 U.S. 52, 61 S. Ct. 399, 401, 85 L. Ed. 581 (1941); *Pacific Gas and Electric Co. v. State Energy Resources Conservation and Dev. Comm'n.*, 461 U.S. 190, 103 S. Ct. 1713, 1722, 75 L. Ed. 2d 752 (1983); and *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 104 S. Ct. 615, 621, 78 L. Ed. 2d 443 (1984). As this court stated in *Silkwood v. Kerr-McGee*, "it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injuried by illegal conduct." *Silkwood*, at page 454. Since the enactment of the FDCA in 1938, our courts have allowed a citizen to receive compensatory damages under state tort law for a drug that failed to provide adequate warnings necessary for his protection. There is nothing in the act or regulations issued pursuant to the FDCA that evidences a preemptive intent. The entire court in both the majority and dissenting opinions of *Silkwood v. Kerr-McGee*, supra, found no congressional intent to preempt a state tort law recovery of compensatory damages even though the court had previously concluded that Congress intended to occupy the "entire field of nuclear safety concerns." (*Pacific Gas and Electric*, at page 212)

In addition to the Court's standard preemption analysis, the Fifth Circuit also relied upon the specific FDA regulations which allowed and encouraged Petitioner to add additional warnings to its label "at the earliest possible time" without prior FDA approval.

Clearly, the Fifth Circuit opinion below was correctly decided upon well established principles of this Court and the express language of the statutes and regulations involved.

IV.

THE REGULATIONS CONCERNING CHLORAMPHENICOL HAVE BEEN REPEALED

As previously noted, the questions presented by Petitioner are not worthy of review by this Court because they are based upon false interpretations of the FDCA and the regulations concerning veterinary oral chloramphenicol. In addition, in 1986 the FDA repealed the regulations concerning veterinary oral chloramphenicol and withdrew its approval of the new animal drug applications. 51 Fed. Reg. 1367 (1986). Therefore, this toxic drug is no longer being produced and sold in the liquid form to which Mr. Osburn was exposed, which exposure eventually resulted in his death from leukemia.

Respondent is aware of no other claim involving oral chloramphenicol which is in the judicial process and, would respectfully submit that this case does not warrant the significance of Supreme Court review, although it is obviously extremely significant to the Osburn family.

CONCLUSION

For the foregoing reasons, the Court should deny this Petition for Writ of Certiorari.

Respectfully submitted,

DALE DOUGLAS WILLIAMS
WILLIAMS, PATTILLO & SQUIRES
3501 West Waco Drive
Waco, TX 76710
(817) 752-9966

Counsel of Record for Respondent, Anita Osburn, Individually and as Independent Executrix of the Estate of Clois Dale Osburn, Deceased

WARNING SECTION TO RACHELLE'S PACKAGE INSERT TO VETERINARIAN

WARNINGS:

These chloramphenicol products must not be used in meat, egg, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined.

Chloramphenicol products should not be administered in conjunction with or 2 hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery time.

Some experiments indicate that chloramphenicol causes, in experimental animals, particularly in females, significant disorders in morphology as well as in function of the gonads.